DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 5,2014

Ormco Corporation
C/O Ms. Courtney Clark
Regulatory Affairs Manager, Submissions
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K141611
Trade/Device Name: Lythos Digital Impression System
Regulation Number: 21 CFR 872.3661
Regulation Name: Optical Impression Systems for CAD/CAM
Regulatory Class: II
Product Code: NOF
Dated: November 4, 2014
Received: November 6, 2014

Dear Ms. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141611

Device Name
Lythos Digital Impression System

Indications for Use *(Describe)*
The Lythos Digital Impression System in an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate or stone models. The Lythos Digital Impression System is intended for use in conjunction with the production of orthodontic and restorative dental appliances, including orthodontic aligners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5. 510(k) SUMMARY

Lythos Digital Impression System

1. Submitter Information:

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

Contact Person: Courtney Clark
Telephone Number: 714-516-7426
Fax Number: 714-516-7472

Date Prepared: 3 December 2014

2. Device Name:

- Proprietary Name: Lythos Digital Impression System
- Classification Name: System, Optical Impression, Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations
- Regulation Description: Optical Impression Systems for CAD/CAM
- CFR Number: 872.3661
- Device Class: II
- Product Code: NOF

3. Predicate Device:

The Lythos Digital Impression System is substantially equivalent to the legally marketed device Digital Impression System K122065 cleared on February 8, 2013, product code NOF.

4. Description of Device:

The Lythos Digital Impression System (DIS) is an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate or stone models. The Lythos DIS is intended for use in conjunction with the production of orthodontic and restorative dental appliances, including orthodontic aligners.

The Lythos DIS is a point-of-care turnkey imaging system used in the dental industry; the intra-oral wand hardware and personal computer (PC) based software form an integrated system that produces accurate, high resolution three dimensional (3D) digital images. The

end result of an intra-oral patient scan is a 3D digital impression data file that accurately describes the surfaces of teeth, gingiva, and palate within a patient's oral cavity, or the surfaces of a stone model.

The system consists of a handheld wand connected to a computer which is housed in a base unit. The computer contains proprietary software to acquire, process, and store the digital 3D image data. Patient information is entered into the software using a touch screen monitor connected to the computer. To capture a 3D image of the patient's dental arch and/or bite, the operator moves the wand along the surface of the teeth to be scanned. A video camera inside the wand captures images of the teeth surfaces. Algorithms in the software process these images into a 3D image and display the 3D image on the computer monitor in real time. The software also saves the 3D image data and identifying patient information to be used by orthodontic or restorative appliance manufacturers to design and manufacture customized appliances. The Lythos DIS device is also equipped with wireless network capability for secure transfer of the 3D image data to the orthodontic or restorative appliance manufacturer.

The Lythos DIS is only used to gather the topography of the mouth and teeth, and to upload the data file (.stl) to the data cloud. The data is available to the licensed dental professional to send to a third party manufacturer. The Lythos DIS .stl data file is used in conjunction with CAD/CAM or 3D printing manufacturing processes. The proposed Lythos DIS is not used for the design, diagnosis or treatment planning of orthodontic aligners.

5. Statement of Intended Use:

The Lythos Digital Impression System in an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate or stone models. The Lythos Digital Impression System is intended for use in conjunction with the production of orthodontic and restorative dental appliances, including orthodontic aligners.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The technological characteristics of the proposed Lythos DIS are very similar to the predicate device, Digital Impression System (K122065). The indications for use have been expanded to include restoratives and orthodontic aligners. There are no substantial technical or functional differences between the Lythos DIS and the predicate (K122065) device. See Table 1 below for technological characteristics and comparisons of the CAD/CAM devices.

Table 1: Comparison of Proposed and Predicate Devices

Element	Digital Impression System K122065	Lythos Digital Impression System
Indications for Use	The Digital Impression System for Orthodontic Use is an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate. The Digital Impression System is intended for use in conjunction with the production of orthodontic appliances.	The Lythos Digital Impression System is an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate or **stone models**. The Lythos Digital Impression System is intended for use in conjunction with the production of orthodontic and **restorative dental appliances**, **including orthodontic aligners**.
Target users	Dental Professionals trained in orthodontics	Dental Professionals
Anatomical Sites	Upper and lower arches of teeth, left and right bite	Upper and lower arches of teeth, left and right bite
Technique to produce 3D images	Interferometry measurement of video camera images	Interferometry measurement of video camera images
Light used for illumination	Blue-violet (405 nm)	Blue-violet (405 nm)
Light source	Diode (laser)	Diode (laser)
Tooth coating	No tooth coating required	Optional tooth coating
Components	Handheld scanning wand containing a high accuracy video camera	Handheld scanning wand containing a high accuracy video camera
Components	Computer mounted in housing that can be moved from room to room	Computer mounted in housing that can be moved from room to room
Components	Cable connecting wand with computer	Cable connecting wand with computer
Components	Touch screen monitor	Touch screen monitor
Key characteristics	Handheld wand is moved over the teeth to acquire 3D images	Handheld wand is moved over the teeth to acquire 3D images
Key characteristics	Real-time display of 3D images while patient is being scanned	Real-time display of 3D images while patient is being scanned
Device Output	Output is a software file that can be used as input to CAD/CAM dental	Output is a software file that can be used as input to

Element	Digital Impression System K122065	Lythos Digital Impression System
	processes	CAD/CAM dental processes
Storage Temperature	Storage Temp = -10C - +50C	Storage Temp = -10C - +50C
Operating Temperature and Humidity	Operating Temp = +10C - +35C, Operating Humidity = 30-85% non-condensing	Operating Temp = +10C - +35C, Operating Humidity = 30-85% non-condensing
Patient contact areas; cross-contamination control	Wand tip is single use and disposable	Wand tip is single use and disposable
Operator contact areas - cross-contamination control	Surfaces disinfected using CaviCide	Surfaces disinfected using CaviCide
Checks of software and hardware function	Scan of verification target	Scan of verification target
Biocompatibility testing of patient contact areas	Passed based on ISO 10993-1:2009 Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process	Has not changed since predicate (K122065)
Sterilization	Validated parameters for wrapped per ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities	Validated parameters for wrapped per ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
Safety Testing	IEC 60601-1, IEC 60601-1-2, IEC 62366	IEC 60601-1, IEC 60601-1-2, IEC 62366
Internal temperature	Upper temp 85	Upper temp 60
Drives	500 GB HD – disk based drive	120 GB SSD – solid state drive
Memory	8GB Ram	16 GB Ram

Non-Clinical Performance Data

The sterilization of the reusable tip assembly for the Lythos Digital Impression System has been validated using the following standards

- AAMI TIR 12: 2010 Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Manufacturers
- ANSI/AAMI ST 79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI TIR 39: 2009 Guidance on selecting microbial challenge and inoculation sites for sterilization validation of medical devices

- ISO 17665-1:2006 Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Electromagnetic compatibility testing was performed in accordance with:

- IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2004 Medical electrical equipment – Part 1-2: General requirements for
- basic safety and essential performance – Electromagnetic compatibility
- IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices
- IEC 62366:2007 Medical devices – Application of usability engineering to medical devices

Additional testing was performed as recommended by the following guidance documents:

- FDA guidance for *Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations*
- FDA guidance for *the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)*
- FDA guidance for *Off-The-Shelf Software Use in Medical Devices (September 9, 1999)*
- FDA draft guidance for *Content of Premarket Submissions for Management of Cybersecurity in Medical devices (June 14, 2013)*
- ISTA Procedure 2A: Partial Simulation Performance Tests, shipping validation testing was performed.
- Internal specification and testing for Aligner Accuracy
- Internal specification and testing for Lythos Accuracy
- Internal specification and testing to verify use of Surface Enhancement Products

Accuracy testing was performed per internal methods to demonstrate substantial equivalence between the proposed Lythos DIS and the predicate (K122065). The results of the non-clinical performance testing conclude that the Lythos DIS is safe and effective for its intended use.

Clinical Performance Data

No human clinical data has been provided to support substantial equivalence.

Conclusion as to Substantial Equivalence

The similarities in design, function, safety and intended use of the Lythos Digital Impression System with the legally marketed predicate Digital Impression System (K122065**)** support substantial equivalence.